



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0128] (formerly Docket No. 2007D-0396)

Detecting and Evaluating Drug-Induced Liver Injury; What's Normal, What's Not, and What Should We Do About It?; Public Conference; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference entitled "Detecting and Evaluating Drug-Induced Liver Injury; What's Normal, What's Not, and What Should We Do About It?" This conference will be cosponsored with the Critical Path Institute (C-Path) and the Pharmaceutical Research and Manufacturers of America. Its purpose is to discuss, debate, and build consensus among stakeholders in the pharmaceutical industry, academia, health care providers, patient groups, and regulatory bodies on how best to detect and assess the severity, extent, and likelihood of drug causation of liver injury and dysfunction in people using drugs for any medical purpose.

DATES: The public conference will be held on March 20, 2013, from 8 a.m. to 6 p.m. and March 21, 2013, from 8 a.m. until 4 p.m.

ADDRESSES: The conference will take place at the Marriott Inn & Conference Center, University of Maryland University College, 3501 University Blvd., East Hyattsville, MD 20783.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In July 2009, FDA announced the availability of guidance for industry entitled “Drug-Induced Liver Injury: Premarketing Clinical Evaluation” (74 FR 38035; July 30, 2009). This guidance explained that drug-induced liver injury (DILI) was the most frequent cause of safety-related drug marketing withdrawals for the past 50 years and that hepatotoxicity has limited use of many drugs that have been approved and prevented the approval of others. It discusses methods of detecting DILI by periodic tests of serum enzyme activities and bilirubin concentration, and how changes in the results of those laboratory tests over time, along with symptoms and physical findings, may be used to estimate severity of the injury. It suggests some “stopping rules” for interrupting drug treatment, and the need to obtain sufficient clinical information to assess causation. FDA published a draft of this guidance in 2006, and comments on the draft were taken into consideration when issuing the final guidance in July 2009 (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM174090.pdf>). FDA is now interested in obtaining stakeholder input on the issues addressed in this guidance, including comments regarding potential revisions to the guidance.

II. The Public Conference

A. Why Are We Holding This Conference?

The purpose of the 2013 conference is to invite participants to present their data and views, and to hold open discussion.

B. Registration, Transcripts, and Additional Information on This Conference and Its Predecessors

A registration fee (\$600 for industry registrants and \$300 for Federal Government and academic registrants) will be charged to help defray the costs of renting meeting spaces and the meals and snacks provided. The fee will also be used to cover travel costs incurred by invited academic (but not Government or Industry) speakers and other expenses. The registration process will be handled by C-Path, an independent, nonprofit organization established in 2005 with public and private philanthropic support from the southern Arizona community, Science Foundation Arizona, and FDA.

The presentations and discussions will be transcribed and published on the Internet for public availability after minor editing by the organizers of the meeting.

Additional information on the conference, program, and registration procedures may be obtained on the Internet at <http://www.c-path.org>, and also at <http://www.fda.gov> by typing into the search box “liver toxicity”. (FDA has verified the C-Path Web site address, but is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.) Material presented at past programs (from 1999 to 2012) may be accessed at www.aasld.org. Click on Education/Training and then scroll down to “Drug Induced Liver Injury 2012 Program.”

Dated: January 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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